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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,536	11/28/2001	Jesus W. Casas-Bejar	P-7109.03 C1	6231

27581 7590 03/09/2004

MEDTRONIC, INC.  
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MINNEAPOLIS, MN 55432-5604

EXAMINER
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THISSELL, JEREMY

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/09/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/998,536

Applicant(s)

CASAS-BEJAR ET AL.

Examiner

Jeremy T. Thissell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11, 12, 26, 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11, 12, 26, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Specification***

The specification is no longer objected to because of the list of references. Although there is no rule preventing such a list, applicant should note that extensive lists such as this one should not be placed in the specification as they are merely a duplication of the listing on the face of the patent. Discussion of background art in the specification is proper. Listing references in the specification, without further discussion, when the same references are also submitted via a form PTO-1449 is nothing more than a replication of the list of cited references on the face of the file.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 11, 12, 26, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724) in view of Fearnot et al (US 5,609,629).

Helmus teaches substantially all the claimed subject matter including an implantable medical device (figure 1, col. 3, line 31), having a tissue-contacting surface formed of polyurethane or silicone (col. 2, lines 41-42) which has a drug such as

Art Unit: 3763

heparin (col. 6, line 51) or a steroid (col. 6, line 55) intimately mixed into it (col. 4, lines 20-24 and col. 9, lines 45-46).

Note that col. 7, lines 57-62 specify the OUTER layer, not the reservoir layer. In col. 7, lines 57-62, Helmus teaches that the agent in the outer layer is put there to produce a "gradual release effect" alluding to the slower release of the agent at first from the outer layer and gradual increase in the release rate as the more concentrated stores of the same agent start to seep through the outer layer from the inner reservoir layer. Since this teaches that the agent in the outer layer can be the same as in the inner layer, Helmus' teaching of the reservoir agent being a steroid (col. 6, line 55) is interpreted as referring to physiologically active agents in BOTH the reservoir and outer layer.

Helmus teaches all the claimed subject matter except for the steroid being a glucocorticosteroid such as dexamethasone. Fearnot teaches the use of dexamethasone in a drug embedded outer layer of a catheter. It would have been obvious to one of ordinary skill in the art to use dexamethasone as taught by Fearnot as one of the steroids broadly mentioned by Helmus (col. 6, line 54-55) since dexamethasone is a well-known anti-inflammatory steroid, and as demonstrated by Helmus it is known to use it as the bioactive component of a bioactive surface on a catheter.

With regard to the method claims, claim 26, which claims a method of use, claims only one broad method step of "implanting," the rest is merely structure. Claims

Art Unit: 3763

30-32, and 35 merely claim the basic assembly steps necessary to put anything together (e.g. "coupling"). Again, the rest is merely structure.

### ***Response to Arguments***

Again, Applicant's attention is called to the Examiner's remarks in parent application 09/063,227 in office actions made therein. Applicant's position hinges on the argument that the Helmus reference does not teach that the agent is "intimately mixed." Applicant seems to want this expression, "intimately mixed," to mean something narrower than their own specification sets forth. Applicant argues that the fact that the agent in Helmus leaves voids behind when it elutes from the substrate means that the agent was not "intimately mixed." However, on page 13 of applicant's own specification, their description commencing on line 26 discusses the scope of "intimately mixed." The specification indicates that the agent and polymer, "are intimately mixed either by [1] **blending** or [2] using a solvent in which they are both soluble . . . ." Applicant appears to be arguing that the term "intimately mixed" means only the second possibility [2], that is, use of a solvent. However, the specification clearly indicates that it is possible to achieve intimate mixing by simply blending the two [1], a procedure explicitly taught by Helmus.

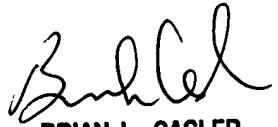
***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for all fax communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt  
March 6, 2004

  
**BRIAN L. CASLER**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**